

510(K) SUMMARY

K130569, 510(k) Summary

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Contact Information

Submitter's Name and Address: TRANSLATIONAL RESEARCH INSTITUTE
3420 S Mercy Road, #312
Gilbert, Arizona 85297
Tel: 480-726-1904 / Fax: 480-612-0641

Name of Contact Person: DeAnn Dana, Project Manager
Translational Research Institute
3420 S Mercy Road, #312
Gilbert, AZ 85297
Tel: 480-726-1904 / Fax: 480-612-0641

Date Summary was Prepared: October 14, 2013

Name of Device

Name of the Device: ND™ Nabil Dib Infusion Catheter
Trade or Proprietary Name: ND™ Nabil Dib Infusion Catheter
Common or Usual Name: Infusion Catheter
Classification Name: Continuous Flush Catheter
CFR Reference: 21 CFR 870.1210
Product Code: KRA
Regulatory Class: Class II

Predicate Device

510(K)	MANUFACTURER	DEVICE	APPROVAL DATE
K081147	Vascular Designs	IsoFlow Infusion Catheter	05-29-09

Device Description

The ND Infusion Catheter is a multilumen (3) and multichannel (6) balloon catheter designed to isolate a specific treatment region from blood flow while directing infusion of fluids into the specified region. The catheter has a length of 135cm and diameter of 3F, and is intended to be used with a 6F or larger guide catheter along with a 0.014" rapid exchange guide wire for positioning the catheter in the desired region.

The bifurcated proximal hub provides for the following functionality:

- 1) Balloon Port
 - Inflation of a compliant balloon to regulate blood flow during therapy infusion; target vessel diameter = 2.0 - 4.5 mm.
 - Balloon is prepared via a 3-way stopcock connection using a 10cc syringe and inflated using a 50:50 contrast/saline solution delivered via a 1cc syringe for precise inflation under fluoroscopic guidance.
- 2) Infusion Port
 - Infusion of a therapeutic agent into the vasculature through multiple fluid channels (each with diameter = 0.006").
 - Physician-specified fluid is administered through the infusion port via a 1-way stopcock connection using a 1cc syringe.

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The catheter is designed with 3 shaft transitions. As a result, the catheter has 4 contiguous segments: PROXIMAL, MID, EXPANSION, and DISTAL.

SEGMENT	FUNCTIONALITY
PROXIMAL	Two lumens in the PROXIMAL segment -- for fluid infusion and balloon inflation -- extend from the bifurcated hub to the MID section.
MID	MID section includes the guidewire Rx port and lumen, and the balloon located distally. The balloon is compliant and designed to expand to accommodate blood vessels with diameters of 2.0 - 4.5 mm while regulating blood flow during infusion.
EXPANSION	EXPANSION segment extends distally from balloon towards the catheter tip and is designed to provide for volumetric expansion of infusate.
DISTAL	In DISTAL segment, infusion lumen divides into 6 independent channels (0.006") delivering infusate to target region at multichannel tip.

Radiopaque marker bands at each end of the balloon and at the distal tip allow for catheter positioning under fluoroscopic guidance.

Indications for Use

The ND Infusion Catheter is a multi-channel balloon catheter designed to isolate a specific vascular treatment region from blood flow while allowing infusion of physician-specified fluids into the target region.

Comparison to Predicate

ND Infusion Catheter vs. Predicate Device

PARAMETER	ND Infusion Catheter	IsoFlow Infusion Catheter
Length	135 cm	150 cm
Diameter	2.4F	3.5F
Number of Lumens	3	3
Number of Infusion Ports	6	3
Materials	Shaft -- Pebax Balloon -- Pellethane	Not known

Technical Testing

The results of bench testing provide reasonable assurance that the device has been designed and performs in conformance to the requirements for its intended use. The technical testing included (but was not limited to) the following:

- Balloon Fatigue
- Balloon Burst Testing
- Balloon Inflation/Deflation
- Balloon Radial Force Testing
- Track Force Testing
- Torque Strength Test
- Tensile Testing
- Separation Force at Break
- Flexibility-Kink Resistance Test
- Liquid Leakage Under Pressure

Biocompatibility

Blood-contacting materials were tested for biocompatibility as summarized below.

TEST	RESULTS	CONCLUSIONS
Cytotoxicity -- L929 MEM Elution Test	Test article meets requirements of the test and is not considered to have a cytotoxic effect.	Non-Cytotoxic
Cytotoxicity -- L929 Neutral Red Uptake Test	Test article meets requirements of the test and is not considered to have a cytotoxic effect.	Non-Cytotoxic
Sensitization -- Kligman Maximization Test	Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.	Non-Sensitizing
Irritation -- Intracutaneous Injection Test	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.	Non-Irritating
Systemic Toxicity -- Systemic Injection Test	The test article did not induce a significantly greater biological reaction than the control extracts, when tested in Swiss Albino mice.	Nontoxic
Genotoxicity -- S Typhimurium & E Coli Reverse Mutation	The mean number of revertants per plate was calculated for the test article extracts, and for the negative and positive control articles. A statistically significant increase in the number of colonies was not observed with the test article.	Non-Genotoxic
Hemolysis -- Rabbit Blood	The test article meets the requirements of the test and is not considered hemolytic.	Non-Hemolytic
Thrombogenicity -- Study in Dogs	Minimal thrombosis with a Grade of 0 (a very small clot is acceptable) was observed in 2/2 test sites and in 2/2 control sites; the amount of thrombosis was not considered significant.	Non-Thrombogenic
Complement Activation Assay	The test article meets the requirements of the test and is not considered having activated the complement system in human plasma.	Non-Complement Activating
Coagulation -- Unactivated PTT Assay	The test article meets the requirements of the test and is not considered having an effect on the coagulation of human plasma via UPTT.	Non-Coagulating
Hemocompatibility -- In Vitro Assay	The test article meets the requirements of the test and is not considered having an effect on selected hematological parameters.	Hemocompatible

Animal Studies

An acute animal study in the swine arterial vasculature catheter demonstrated excellent trackability, pushability, balloon inflation, deflation, removal, infusion of fluid through the infusion lumen, marker band visibility, and no hub or catheter leak. There was no vascular injury in any of the vessels that were evaluated (LCx, LAD, RCA, Renal, Femoral, Iliac, Carotid) as assessed by angiography and gross examination. In summary, this study robustly validated the functional performance and safety of the ND Infusion Catheter.

The results of the Technical Testing, Biomaterial Assessments, and Animals Study summarized above did not raise new safety or performance questions.

Conclusions

Based on the above testing, the ND Infusion Catheter is substantially equivalent to devices legally marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 15, 2013

Translational Research Institute
DeAnn Dana, RN
Project Manager
3420 S Mercy Rd #312
Gilbert, AZ 85297 US

Re: K130569
Trade/Device Name: ND™ Nabil Dib Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 15, 2013
Received: October 16, 2013

Dear Ms. Dana,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Device Name: ND™ Nabil Dib Infusion Catheter

510(k) Number: K130569

Indications for Use: The ND Infusion Catheter is a multi-channel balloon catheter designed to isolate a specific vascular treatment region from blood flow while allowing infusion of physician-specified fluids into the target region.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION

Prescription Use X

OR

Over-The-Counter Use

(Per 21 CFR 801.109)

M. G. Wilhelmsen